

REMARKS

Claims 1-23 are currently pending. Claims 1-4 and 6-9 have been amended. The amendments to claims 1-4 and 6-9 do not constitute new matter. Claims 5 and 12 have been canceled.

The Examiner has rejected claims 3-23 under 35 U.S.C. § 112, first paragraph, as lacking support in the written description. The Examiner has rejected claims 2-23 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner has rejected claims 1-4 and 7 under 35 U.S.C. § 102(b) as anticipated by Bevan et al. (GenBank Accession No. AL022224) (“Bevan”). For the reasons detailed below, the rejections should be withdrawn and the claims allowed to issue. Entry of the foregoing amendments is respectfully requested.

Objections To The Specification

The Examiner has objected to the specification due to a typographical error in the abstract of the specification. Applicants note that the abstract has been amended to correct the error as requested by the Examiner. The Examiner has also objected to the specification due to the inclusion of an embedded hyperlink. The Examiner appears to be referring to the hyperlink cited on page 3, paragraph [0008] of the application. Applicants note that reference to the hyperlink has been deleted.

Based upon the foregoing, Applicants submit that the Examiner’s objections have been obviated, and respectfully request withdrawal of the rejections.

The Claims Are Supported By The Specification

The Examiner has rejected claims 3-23 under 35 U.S.C. § 112, first paragraph, as lacking support in the written description. The Examiner states that the specification does not disclose “variant[] promoter sequences that have at least 70% sequence identity to SEQ ID NO:1, or that hybridize to SEQ ID NO:1 under high stringency conditions.” The Examiner asserts that the specification does not describe a representative number of species within the scope of the claimed genus, nor structural features unique to that genus which are correlated to the variant’s promoter activity.

Applicants note that the claims have been amended to now specify 90% homology, or to identify specific high stringency conditions. For example, claim 4 now recites “wherein high stringency conditions comprise incubation at 42°C in 50% formamide.” Support for these amendments can be found in the specification, for example, at page 3, para. 0008 (the sequence has “at least 90%... identity to the sequence of SEQ ID NO:1 or a fragment thereof that has promoter activity”), and at page 3, para. 0009 (“High stringency conditions are defined herein as... 42°C in 50% formamide”). Applicants submit that the specification provides ample support for the claims, as amended, including relevant identifying characteristics coupled to known functional characteristics. See MPEP § 2163. The specification provides relevant identifying characteristics in the form of a specific sequence (SEQ ID NO:1) and a high degree of homology to the disclosed sequence (90%). The specification further discloses specific high stringency hybridization conditions to identify members of the claimed genus. The disclosed sequence is further described to possess promoter activity, which is a functional property associated with the identified structural characteristics. While the specification does not disclose specific sequences which are of 90% homology and hybridize under the specified stringency conditions, it would be

well within the capabilities of a person of ordinary skill in the art to identify members of the claimed genus based upon the present disclosure.

Based upon the foregoing, Applicants submit that the present invention is well-supported by the specification, and respectfully request withdrawal of the rejection.

The Claims Are Enabled

The Examiner has rejected claims 2-23 under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that the specification does not provide reasonable enablement for isolated nucleic acid sequences other than SEQ ID NO:2. The Examiner states that the “full scope of the claimed invention is not enabled because it is unpredictable whether fragments or variants of SEQ ID NO:1 would retain promoter function.” The Examiner further states that the specification does not provide “the identity and location of key nucleotides and motifs required for promoter function.” The Examiner asserts that, absent such a teaching, it would require undue experimentation to practice the claimed invention.

Applicants disagree with the Examiner, and submit that it would require no more than routine experimentation to identify sequences with promoter activity. The present specification provides ample guidance for isolating nucleic acid sequences and assaying them for promoter activity. For example, see Examples at pages 12, para. 0029 to page 14, para. 0036. The methods disclosed are common and well known in the art. The specification clearly teaches the production of constructs comprising a putative promoter and a reporter gene, and further describes a method of testing the construct for promoter activity. See page 13, para. 0032 to page 14, para. 0034. Based upon this disclosure, it would not require undue experimentation for a person of ordinary skill in the art to determine whether a given portion of SEQ ID NO:1

exhibits promoter activity. It is well within the abilities of a person of ordinary skill in the art to generate fragments of the sequence and to test them for promoter activity based upon the teachings of the present specification, particularly given the relatively short length of SEQ ID NO:1 (2130 base pairs).¹

Although the Examiner asserts that “the identity and location of key nucleotides and motifs required for promoter function” have not been identified, and that such testing requires excessive “trial and error,” Applicants submit that the quantity of experimentation is reasonable in the present invention. Applicants note that “a considerable amount of experimentation is permissible, if it is merely routine, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed.” See MPEP 2164.05(b). As noted above, the present invention provides ample guidance on how the experimentation should proceed, by providing a specific sequence from which to obtain test sequences, narrowing the potential number of test sequences by identifying a particular level of homology and/or hybridization, by disclosing a specific reporter gene to link the test sequence to, and teaching specific plants and methods for assaying the test sequences with. Based upon this disclosure, assaying even a large number of test sequences would require no more than routine experimentation.

Based upon the foregoing, Applicants submit that the present invention is enabled, and respectfully request withdrawal of the rejection.

¹ Applicants submit that such techniques for generating fragments of SEQ ID NO: 1 are well-known in the art, and accordingly need not be explicitly recited because “the specification need not disclose what is well-known to those skilled in the art.” MPEP § 2164.05(a).

The Claims Are Novel

The Examiner has rejected claims 1-4 and 7 under 35 U.S.C. § 102(b) as anticipated by Bevan *et al.* (GenBank Accession No. AL022224) ("Bevan"). The Examiner states that Bevan teaches an isolated nucleic acid comprising SEQ ID NO:1, and that the nucleic acid taught by Bevan inherently encompasses fragments of SEQ ID NO:1.

Applicants submit that Bevan does not disclose all of the limitations of the present claims, as amended. Anticipation requires that each and every element of the rejected claim(s) be disclosed in a single prior art reference. See M.P.E.P. § 2131 (8th Ed. Rev. 2, May 2004). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Every element of the claimed invention must literally be present, arranged as in the claim. *Perkin Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894, 221 USPQ 669, 673 (Fed. Cir. 1984).

Applicants note that claims 1-4 have been amended to incorporate the limitations of claim 5, and now recite "an isolated nucleic acid... operably linked to a heterologous nucleic acid." Support for this amendment can be found, for example, in the specification at page 1, para. 0004, and at page 3, para. 0010, and in original claim 5. Bevan merely discloses a large nucleic acid sequence, without identification of any functional elements. Bevan provides very little description of the sequence, and does not single out or otherwise identify the sequence of SEQ ID NO:1. The sequence of Bevan is also derived solely from *Arabidopsis thaliana* Columbia, and does not include any heterologous sequences. See Bevan under "source." Accordingly, Bevan does not teach an isolate nucleic acid of the sequence SEQ ID NO:1, since Bevan does not single out or otherwise distinguish the sequence of SEQ ID NO:1. Furthermore,

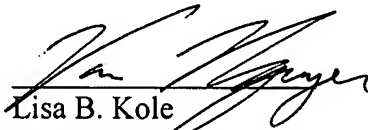
Bevan does not disclose the presence of any heterologous sequence within the disclosed sequence, and therefore does not teach operable linkage of SEQ ID NO:1 to a heterologous nucleic acid. Accordingly, Bevan does not teach all of the limitations of the present invention, and cannot be the basis for an anticipation rejection.

Based upon the foregoing, Applicants submit that the present invention is novel, and respectfully request withdrawal of the rejection.

CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. The Applicant believes that the inventions described and defined by claims 1-23 are patentable over the rejections of the Examiner. Withdrawal of all rejections and reconsideration of the amended claims is requested. An early allowance is earnestly sought.

Respectfully submitted,


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